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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Serial No: 09/593,914 Confirmation No: 8319
Date Filed: June 14, 2000
Application Title: Probes, Probe Sets, Methods And Kits Pertaining To The
Detection, Identification And/Or Enumeration Of Yeast;
Particularly In Wine
Applicants: Hyldig-Nielsen et al
Group Art Unit: 1634
Examiner: C. Myers
Action Date: February 25, 2003
Action Type: Third Office Action On Merits - FINAL
Certified Mail No.: 7003 0500 0000 1731 7079

Certificate of Mailing Pursuant to:
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop: AF, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 22nd day of August, 2003.

Brian D. Gildea

Reg. No. 39,995

DECLARATION OF DR. HENRIK STENDER
UNDER 37 C.F.R. § 1.132

Commissioner for Patents
Dear Sir or Madam:

I, Dr. Henrik Stender of Fasanhaven 5, DK-2820 Gentofte, Denmark do hereby declare and state that:

1. I am presently employed as Vice President of Research & Development of AdvanDx, Inc. and have been in this position since August 2002;


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2. I was formerly employed at Boston Probes & Applied Biosystems from May, 1998 until August, 2002 in various positions, including Director of Microbiology;
3. Before that I was employed at Dako A/S Denmark as Research Scientist from July, 1992 until May, 1998;
4. I received my doctorate from Technical University of Denmark in 1992 in the area of Immunology;
5. I have been employed as a scientist/manager in the field of assay development for a total of 11 years;
6. I am a co-inventor of the above captioned patent application and I have reviewed the claims as currently pending in the application;
7. I have reviewed the Office Action dated February 25, 2003 and the examiners arguments set forth therein;
8. I am a co-inventor of PCT/DK97/00425 (WO98/15648) entitled: "Novel Probes For The Detection Of Mycobacteria", referred to by the Examiner in the above captioned application as Stender (1998) and am familiar with its contents;
9. I have reviewed Kosse et al., Systems. Appl. Microbiol. 20: 468-480 (1997);
10. I have reviewed Amann et al., Applied and Environmental Microbiology 58(9): 3007-3011 (1992);
11. Based upon my review of the Amann et al. reference, I believe that: 1) Amann et al. teach that it was well accepted, at the time of their publication, that enzyme-linked (labeled) probes COULD NOT readily penetrate the cell wall of yeast; 2) Amann et al. had no success with getting enzyme-labeled probes into yeast; and 3) Amann et

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- al. would tend to dissuade one of skill in the art from attempting to use an enzyme-linked probe to analysis a yeast in an in-situ based assay;
12. Kosse et al. would not, in view of Amann et al., tend to motivate the application of enzyme-linked probes to in-situ assays for yeasts because the reference does not address this particular assay format;
13. Stender (1998) would not, in view of Amann et al. tend to motive the application of enzyme-linked probes to in-situ assays for yeasts because the reference does not address yeasts;
14. One of skill in the art at the time of the present invention would not have a reasonable expectation of successfully applying enzyme-linked probes to the determination of yeast in an in-situ based assay because there was inadequate teaching available as to how to permeablize the cell wall of the yeast to these large molecules.

I further declare that all statements made in this Declaration are true and that all statements made on information and belief are believed to be true. Moreover, these statements were made with the knowledge that willful false statements and the like made by me are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Henrik Stender

8/21 - 2003

Date